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**DECLARATION**

(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL,  
CONTINUATION, OR C-I-P)

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As a below named inventor, I hereby declare that:

**TYPE OF DECLARATION**

This declaration is of the following type:

(check one applicable item below)

☒ original.

☐ design.

**NOTE:** *With the exception of a supplemental oath or declaration submitted in a reissue, a supplemental oath or declaration is not treated as an amendment under 37 CFR 1.312 (Amendments after allowance). M.P.E.P. § 714.16, 7th Edition.*

☐ supplemental.

**NOTE:** *If the declaration is for an International Application being filed as a divisional, continuation or continuation-in-part application, do not check next item; check appropriate one of last three items.*

☐ national stage of PCT.

**NOTE:** *If one of the following 3 items apply, then complete and also attach ADDED PAGES FOR DIVISIONAL, CONTINUATION OR C-I-P.*

**NOTE:** *See 37 C.F.R. § 1.63(d) (continued prosecution application) for use of a prior nonprovisional application declaration in the continuation or divisional application being filed on behalf of the same or fewer of the inventors named in the prior application.*

☐ divisional.

☐ continuation.

**NOTE:** *Where an application discloses and claims subject matter not disclosed in the prior application, or a continuation or divisional application names an inventor not named in the prior application, a continuation-in-part application must be filed under 37 C.F.R. § 1.53(b) (application filing requirements – nonprovisional application).*

☐ continuation-in-part (C-I-P).

**INVENTORSHIP IDENTIFICATION**

**WARNING:** *If the inventors are each not the inventors of all the claims, an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.*

My residence, post office address and citizenship are as stated below, next to my name. I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter that is claimed, and for which a patent is sought on the invention entitled

**TITLE OF INVENTION**

DRUG RELEASE (DELIVERY SYSTEM)

## SPECIFICATION IDENTIFICATION

the specification of which:

(complete (a), (b), or (c))

(a) ☒ is attached hereto.

NOTE: "The following combinations of information supplied in an oath or declaration filed on the application filing date with a specification are acceptable as minimums for identifying a specification and compliance with any one of the items below will be accepted as complying with the identification requirement of 37 CFR 1.63:

"(1) name of inventor(s), and reference to an attached specification which is both attached to the oath or declaration at the time of execution and submitted with the oath or declaration on filing;

"(2) name of inventor(s), and attorney docket number which was on the specification as filed; or

"(3) name of inventor(s), and title which was on the specification as filed."

Notice of July 13, 1995 (1177 O.G. 60).

(b) ☐ was filed on , as ☐ Serial No. 0/ and was amended on (if applicable).

NOTE: Amendments filed after the original papers are deposited with the PTO that contain new matter are not accorded a filing date by being referred to in the declaration. Accordingly, the amendments involved are those filed with the application papers or, in the case of a supplemental declaration, are those amendments claiming matter not encompassed in the original statement of invention or claims. See 37 C.F.R. § 1.67:

NOTE: "The following combinations of information supplied in an oath or declaration filed after the filing date are acceptable as minimums for identifying a specification and compliance with any one of the items below will be accepted as complying with the identification requirement of 37 CFR 1.63:

"(A) application number (consisting of the series code and the serial number, e.g., 08/123,456);

"(B) serial number and filing date;

"(C) attorney docket number which was on the specification as filed;

"(D) title which was on the specification as filed and reference to an attached specification which is both attached to the oath or declaration at the time of execution and submitted with the oath or declaration; or

"(E) title which was on the specification as filed and accompanied by a cover letter accurately identifying the application for which it was intended by either the application number (consisting of the series code and the serial number, e.g., 08/123,456), or serial number and filing date. Absent any statement(s) to the contrary, it will be presumed that the application filed in the PTO is the application which the inventor(s) executed by signing the oath or declaration."

M.P.E.P. § 601.01(a), 7th Ed.

(c) ☐ was described and claimed in PCT International Application No. , filed on and as amended under PCT Article 19 on (if any).

**SUPPLEMENTAL DECLARATION (37 C.F.R. § 1.67(b))**

*(complete the following where a supplemental declaration is being submitted)*

☐ I hereby declare that the subject matter of the

☐ attached amendment

☐ amendment filed on

was part of my/our invention and was invented before the filing date of the original application, above-identified, for such invention.

**ACKNOWLEDGEMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR**

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information, which is material to patentability as defined in 37, Code of Federal Regulations, § 1.56,

*(also check the following items, if desired)*

☒ and which is material to the examination of this application, namely, information where there is a substantial likelihood that a reasonable Examiner would consider it important in deciding whether to allow the application to issue as a patent, and

☒ in compliance with this duty, there is attached an information disclosure statement, in accordance with 37 C.F.R. § 1.98.

**PRIORITY CLAIM (35 U.S.C. §§ 119(a)-(d))**

**NOTE:** *"The claim to priority need be in no special form and may be made by the attorney or agent if the foreign application is referred to in the oath or declaration as required by § 1.63. The claim for priority and the certified copy of the foreign application specified in 35 U.S.C. 119(b) must be filed in the case of an interference (§ 1.630), when necessary to overcome the date of a reference relied upon by the examiner, when specifically required by the examiner, and in all other situations, before the patent is granted. If the claim for priority or the certified copy of the foreign application is filed after the date the issue fee is paid, it must be accompanied by a petition requesting entry and by the fee set forth in § 1.17(i). If the certified copy is not in the English language, a translation need not be filed except in the case of interference; or when necessary to overcome the date of a reference relied upon by the examiner, or when specifically required by the examiner, in which event an English language translation must be filed together with a statement that the translation of the certified copy is accurate." 37 C.F.R. § 1.55(a).*

I hereby claim foreign priority benefits under Title 35, United States Code, §§ 119(a)-(d) of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

*(complete (d) or (e))*

(d) ☒ no such applications have been filed.

(e) ☐ such applications have been filed as follows.

**NOTE:** *Where item (c) is entered above and the International Application which designated the U.S. itself claimed priority check item (e), enter the details below and make the priority claim.*

**PRIOR FOREIGN/PCT APPLICATION(S) FILED WITHIN 12 MONTHS  
(6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION  
AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. § 119(a)-(d)**

| COUNTRY (OR<br>INDICATE IF PCT) | APPLICATION<br>NUMBER | DATE OF FILING<br>(day, month, year) | PRIORITY CLAIMED<br>UNDER 37 USC 119 |                             |
|---------------------------------|-----------------------|--------------------------------------|--------------------------------------|-----------------------------|
|                                 |                       |                                      | <input type="checkbox"/> YES         | NO <input type="checkbox"/> |
|                                 |                       |                                      | <input type="checkbox"/> YES         | NO <input type="checkbox"/> |
|                                 |                       |                                      | <input type="checkbox"/> YES         | NO <input type="checkbox"/> |
|                                 |                       |                                      | <input type="checkbox"/> YES         | NO <input type="checkbox"/> |
|                                 |                       |                                      | <input type="checkbox"/> YES         | NO <input type="checkbox"/> |
|                                 |                       |                                      | <input type="checkbox"/> YES         | NO <input type="checkbox"/> |

**CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S)  
(34 U.S.C. § 119(e))**

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below:

**PROVISIONAL APPLICATION NUMBER**

60/225,082

**FILING DATE**

August 14, 2000

**CLAIM FOR BENEFIT OF EARLIER US/PCT APPLICATION(S)  
UNDER 35 U.S.C. § 120**

- ☐ The claim for the benefit of any such applications are set forth in the attached ADDED PAGES TO DECLARATION FOR DIVISIONAL, CONTINUATION OR CONTINUATION-IN-PART (C-I-P) APPLICATION.

**Practitioner's Docket No. 41530/28295**

ADDED PAGE TO COMBINED DECLARATION  
AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION  
OR C-I-P APPLICATION

*(complete this part only if this is a divisional, continuation or C-I-P application)*

**CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(S)  
UNDER 35 U.S.C. 120**

I hereby claim the benefit, under Title 35, United States Code, § 120, of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information

☒ that is material to patentability as defined in 37, Code of Federal Regulations, § 1.56

*(also check the following item, if desired)*

☒ and that is material to the examination of this application, namely, information where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent,

that occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application. (37 C.F.R. § 1.63(e)).

*(also check the following item, if desired)*

☐ In compliance with this duty, there is attached an information disclosure statement, in accordance with 37 C.F.R. § 1.98.

| PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S.<br>FOR BENEFIT UNDER 35 USC 120: |                   |                  |          |                    |           |
|---|-------------------|------------------|----------|--------------------|-----------|
| U.S. Applications   |                   |                  |          | Status (check one) |           |
|   | U.S. Applications | U.S. FILING DATE | Patented | Pending            | Abandoned |
| 1.0   |                   |                  |          |                    |           |
| 2.0   |                   |                  |          |                    |           |
| 3.0   |                   |                  |          |                    |           |
| PCT APPLICATIONS DESIGNATING THE U.S.   |                   |                  |          |                    |           |

|    | PCT APPLICATION<br>No. | PCT FILING DATE | U.S.<br>APPLICATION<br>NOS. ASSIGNED<br>(If Any) |
|----|------------------------|-----------------|--|
| 4. |                        |                 | 0. /   |
| 5. |                        |                 | 0. /   |
| 6. |                        |                 | 0. /   |

**35 USC § 119 PRIORITY CLAIM, IF ANY,  
FOR ABOVE LISTED U.S./PCT APPLICATIONS**

| ABOVE<br>APPLICATION<br>NO.                           | DETAILS OF U.S. PROVISIONAL OR FOREIGN APPLICATION<br>FROM WHICH PRIORITY CLAIMED UNDER 35 USC § 119 |                                      |                                     |
|---|--|--------------------------------------|-------------------------------------|
| Please indicate<br>appropriate PCT<br>application no. | Country and<br>Application No.   | Date of filing<br>(day, month, year) | Date of issue<br>(day, month, year) |
| 1.  |  |                                      |                                     |
| 2.  |  |                                      |                                     |
| 3.  |  |                                      |                                     |
| 4.  |  |                                      |                                     |
| 5.  |  |                                      |                                     |
| 6.  |  |                                      |                                     |
| 7.  |  |                                      |                                     |
| 8.  |  |                                      |                                     |

**ALL FOREIGN APPLICATION(S), IF ANY, FILED MORE THAN 12 MONTHS  
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION**

**NOTE:** *If the application filed more than 12 months from the filing date of this application is a PCT filing forming the basis for this application entering the United States as (1) the national stage, or (2) a continuation, divisional, or continuation-in-part, then also complete ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR C-I-P APPLICATION for benefit of the prior U.S. or PCT application(s) under 35 U.S.C. § 120.*

**SEND CORRESPONDENCE TO**

**DIRECT TELEPHONE CALLS TO:**  
(Name and telephone number)

☒ Address

Paul A. Lesko, 314-552-6443

Thompson Coburn LLP, One Firststar Plaza, St. Louis, MO 63101

☒ Customer Number 021888

(complete the following, if applicable)

Since this filing is a ☐ continuation ☐ divisional there is attached hereto a Change of Correspondence Address so that there will be no question as to where the PTO should direct all correspondence.

## DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

## SIGNATURE(S)

**NOTE:** Carefully indicate the family (or last) name, as it should appear on the filing receipt and all other documents.

**NOTE:** Each inventor must be identified by full name, including the family name, and at least one given name without abbreviation together with any other given name or initial, and by his/her residence, post office address and country of citizenship. 37 CFR § 163(a)(3).

**NOTE:** Inventors may execute separate declarations/oaths provided each declaration/oath sets forth all the inventors. Section 1.63(a)(3) requires that a declaration/oath, *inter alia*, identify each inventor and prohibits the execution of separate declarations/oaths which each sets forth only the name of the executing inventor. 62 Fed. Reg. 53,131, 53,142, October 10, 1997.

### Full name of sole or first inventor

John R. Reynolds  
(GIVEN NAME) (MIDDLE INITIAL OR NAME) FAMILY (OR LAST NAME)

Inventor's signature \_\_\_\_\_

Date \_\_\_\_\_ Country of Citizenship U.S.A.

Residence Gainsville, Florida, U.S.A.

Post Office Address 3645 N.W. 24<sup>th</sup> Place, Gainesville, Florida 32605 U.S.A.

### Full name of second joint inventor, if any

Hiep Ly  
(GIVEN NAME)(MIDDLE INITIAL OR NAME)FAMILY (OR LAST NAME)

Inventor's signature \_\_\_\_\_

Date \_\_\_\_\_ Country of Citizenship \_\_\_\_\_

Residence Webster, New York, U.S.A.

Post Office Address 630 Yardley Court, Webster, New York 14580 U.S.

### Full name of third joint inventor, if any

Partick John Kinlen  
(GIVEN NAME) (MIDDLE INITIAL OR NAME) FAMILY (OR LAST NAME)

Inventor's signature \_\_\_\_\_

Date \_\_\_\_\_ Country of Citizenship U.S.A.

Residence Fenton, Missouri, U.S.A.

Post Office Address 1348 Remington Oaks Terrace, Fenton, Missouri 63026 U.S.A.

Full name of fourth joint inventor, if any

Vernod P. Menon  
(GIVEN NAME) (MIDDLE INITIAL OR NAME) FAMILY (OR LAST NAME)

Inventor's signature \_\_\_\_\_

Date \_\_\_\_\_ Country of Citizenship U.S.A.

Residence Woodbury, Minnesota, U.S.A.

Post Office Address 6185 Tahoe Court, Woodbury, Minnesota 55125 U.S.A.

(check proper box(es) for any of the following added page(s)  
that form a part of this declaration)

☒ **Signature** for fourth and subsequent joint inventors. *Number of pages added* 1

\* \* \*

☐ **Signature** by administrator(trix), executor(trix) or legal representative for deceased or incapacitated inventor. *Number of pages added*

\* \* \*

☐ **Signature** for inventor who refuses to sign or cannot be reached by person authorized under 37 CFR 1.47. *Number of pages added*

\* \* \*

☐ Added page for **signature** by one joint inventor on behalf of deceased inventor(s) where legal representative cannot be appointed in time. (37 CFR 1.47)

\* \* \*

☐ Added pages to combined declaration and power of attorney for divisional, continuation, or continuation-in-part (C-I-P) application. *Number of pages added*

\* \* \*

☐ Authorization of practitioner(s) to accept and follow instructions from representative.

\* \* \*

(if no further pages form a part of this Declaration,  
then end this Declaration with this page and check the following item)

☒ **This declaration ends with this page.**